510(K) SUMMARY

MAY 1 3 2013

AG MASS™

510(k) Number K131099

Applicant's Name: **Hospitech Respiration Ltd.**
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Summary 510(k) Preparation Date: April 14, 2013

Trade Name: **AG MASS™**

Device Type **Irrigation Syringe**

Classification: **Regulatory Name:** Powered suction pump

Product Code: JCX

Regulation No: 21 CFR 878.4780

Class: II

Classification Panel: General Hospital

Device Description:

The ***AG MASS™*** is a sterile injection and draining device.
The device is intended to deliver Saline fluid in order to dilute secretions accumulated above the cuff of an Endotracheal Tube and drain out all fluids.
The ***AG MASS™*** contains two syringes of 35 CC and 10 CC that are enclosed within MASS main body and is designed for use with Hospitech's AnapnoGuard ETT.
The ***AG MASS™*** is provided sterile for single use.

Intended Use Statement:

The ***AG MASS™*** Suction Pump System is intended for the application of low-flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	Manufacturer	510k No	Date of approval
Boehirnger Laboratories Suction Pump System	Boehirnger Laboratories	K060277	March 03, 2006
Aardvark nasal irrigation and aspiration device	Aardvark Medical	K082762	Nov. 12 2008
Single Cannula Extended Applicator	Micromedics, Inc.	K102563	March 15, 2011

Performance Standards

AG MASS™ was tested and complies with the following standards:

- **ANSI/AAMI/**ISO 11137-1: 2006 Sterilization of health care products - Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing.

Refer to **Section 5** for the complete list of standards.

Performance Bench Tests

Bench testing demonstrated that the ***AG MASS™*** is as safe and effective as the cleared predicate devices.
The following bench tests were conducted:

- Draining Validation
- ***AG MASS*** prefilled saline syringe- chemical and toxicological assessment
- The device was also tested for Chemical and toxicological assessment (possible leachable and extractable) following the sterilization process and found safe.

Summary of Pre-Clinical and clinical study

The common practice for evacuating secretions that accumulates while using endotracheal tubes is by manually injecting saline with a standard syringe connected to the proximal port of the suction lumen and then applying vacuum to remove the diluted secretions.

The ***AG MASS™*** removes secretions in a similar way to the commonly used syringe, implementing the same technology. The ***AG MASS™*** was tested in bench performance tests and in pre-clinical testing to perform its intended use safely and efficiently. Thus, Hospitech believes that clinical studies are not required to determine the safety and efficacy of the device.

Comparison with the Predicate Device

The ***AG MASS™***, like its primary predicate device – the **Boehirnger Laboratories Suction Pump System** is intended for the removal of infectious materials from the patient's respiratory support system.

The ***AG MASS™*** and its predicate devices, the **Aardvark nasal irrigation and aspiration device** and the ***Single Cannula Extended Applicator***, have the same technological characteristics. Furthermore, the ***AG MASS™*** and the predicate devices have identical or similar technological features as discussed in the substantial equivalence section (**section 8**). Performance testing show compliance of the device with its intended use, and that any minor differences in the design do not raise any new safety and effectiveness issues. Therefore the ***AG MASS™*** is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

May 13, 2013

Hospitech Respiration, Ltd.
% Qsite
Mr. Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

Re: K131099
Trade/Device Name: AG MASS™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: April 17, 2013
Received: April 19, 2013

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K131099

Device Name: *AG MASS™*

Indications for Use: The *AG MASS™* Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131099